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K014220

Summary of Safety and Effectiveness
Device Modification to the T2 Femoral Nail System

Submission Information

Name and Address of the Sponsor of the 510(k) Submission	Howmedica Osteonics Corp 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Karen Ariemma Regulatory Affairs Specialist
Date of Summary Preparation:	December 18, 2001

Device Identification

Proprietary Name:	T2 Femoral Nail System
Common Name:	Intramedullary Nail, Femoral Nail
Classification Name and Reference:	Intramedullary Fixation Rod, 21 CFR §888.3020

Predicate Device Identification

The subject T2 Femoral Nail System is a fracture fixation device comprised of femoral nails and the related locking screws, compression screws, condyle screws/nuts and end caps.

Description of Device Modification

The T2 Condyle Screw and T2 Condyle Screw Nut are being modified to improve the interface between the T2 Condyle Screw and T2 Condyle Screw Nut. This submission covers use of subject T2 Condyle Screw and T2 Condyle Screw Nut with the T2 Tibial Nail. In addition, this submission covers the use of the IC End Caps and Compressions Screws with the T2 Femoral Nail.

Intended Use:

The subject T2 Femoral Nail System is a fracture fixation device comprised of femoral nails and the related locking screws, compression screws, condyle screws/nuts and end caps. The subject device is intended to provide strong and stable internal fracture fixation with minimal soft tissue irritation. This device is utilized as an aid to healing, not as a substitute for normal intact bone and tissue.

Statement of Technological Comparison:

Analysis demonstrates comparable properties of the subject to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 5 2002

Ms. Karen Ariemma
Regulatory Affairs Specialist
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401

Re: K014220
Trade/Device Name: T2 Femoral Nail System
Regulation Number: 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: December 21, 2001
Received: December 26, 2001

Dear Ms. Ariemma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 014220

Device Name: T2 Femoral Nail System

Indications for Use

The T2 Femoral Nail is indicated for long bone fracture fixation specifically femoral fracture fixation, which may include the following:

- Open and closed femoral fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Supracondylar fractures, including those with intra-articular extension
- Ipsilateral femur fractures
- Fractures proximal to a total knee arthroplasty
- Fractures distal to a hip joint
- Nonunions and malunions

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milhizer

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K014220